DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration
Central Region

95148d

New Jersey District
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6008

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

December 14, 2004

File # 05-NWJ-07

Mr. T. James Kin
President
Kinton, Inc.
357 Wilson Avenue
Newark, New Jersey 07105

Dear Mr. Kin:

We inspected your seafood processing facility, located at 357 Wilson Avenue, Newark, New Jersey, on September 9, 13, and 21, 2004. The inspection was conducted to determine your compliance with the seafood Hazard Analysis Critical Control Point (HACCP) regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR Part 123). In accordance with 21 CFR 123.6(g), the failure of a processor to have and implement a HACCP plan that complies with this section, or to otherwise operate in accordance with the requirements of this Part renders the seafood adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). Accordingly, the deviation noted during the inspection causes your fresh tuna products to be adulterated within the meaning of section 402(a)(4) of the Act, in that they were prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You can find the Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

During our inspection, the investigator provided you with the form FDA 483, which presents his evaluation of your firm's performance regarding various aspects of the HACCP requirements. The inspection revealed the following serious deviation from the HACCP regulations:

- You must fully implement the monitoring and recordkeeping procedures identified in your HACCP plan, in order to comply with 21 CFR 123.6(b). However, your firm did not record any monitoring observations at the receiving critical control point (CCP), in order to control the hazard of histamine formation as identified in your HACCP plan for Scombroid species fish. Specifically, your firm receives fresh, whole tuna, which is returned to your facility by your customers. Upon receipt, your firm washes, re-ices, re-boxes, and stores the tuna. The product is then redistributed to other consignees. However, no records were maintained to show that product temperatures or adequacy of ice were monitored and recorded upon your receipt of these products, in accordance with your stated monitoring procedures. Inventory records collected by our investigator during the inspection showed that your firm received, re-iced, repacked, and re-sold fresh tuna returned by your consignees on at least 65 different occasions from August 31, 2004, through September 8, 2004. During our inspection, you advised our investigator that you did not consider the receipt of returned goods intended for resale to be "receiving." Please be advised that with respect to fish or fishery products, processing includes activities such as handing, storing, preparing, and packing. Please see 21 CFR 123.3(k)(1) for the full definition of "processing."

We may take further action if you do not promptly correct this violation. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific actions you are taking to correct this deviation. You should include in your response documentation such as revised HACCP plan(s), revised monitoring procedures, copies of revised monitoring records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining deviations.

This letter may not list all deviations at your facility. You are responsible for ensuring that your facility operates in compliance with the Act, the seafood HACCP regulations, and the Current Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Your response to this letter should be directed to the U.S. Food and Drug Administration, Attention: Richard D. Manney, Compliance Officer at the address and telephone number listed above.

Sincerely,

Douglas I. Ellsworth
District Director
New Jersey District